IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

A. LUKE SMITH, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Defendant.	Civil Action No. _____

COMPLAINT

Plaintiff A. Luke Smith, for his complaint against the above-captioned defendant, alleges as follows:

I. NATURE OF THE ACTION

1. This action is brought pursuant to the Freedom of Information Act ("FOIA" or "the Act"), 5 U.S.C. § 552 (2006), as amended, to compel the production of certain agency documents and records relating to approval of Abbreviated New Drug Applications ("ANDAs") 076565 (Teva), 078057 (Impax), and 078789 (Mylan), which have been improperly withheld from Plaintiff by Defendant Food and Drug Administration ("FDA").

II. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

3. This Court has personal jurisdiction over Defendant under 5. U.S.C. § 552(a)(4)(B). Defendant maintains a continuous and systematic presence in Pennsylvania,

including a District Office located at 900 U.S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106.

4. Venue is proper in this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e) because Plaintiff resides in this District.

III. PARTIES

5. Plaintiff A. Luke Smith submitted a FOIA request to FDA for SBAs relating to ANDAs 076565 (Teva), 078057 (Impax Labs), and 078789 (Mylan).

6. Plaintiff works and resides in this district. Plaintiff is a practicing attorney who works at Faruqi & Faruqi, LLP, 101 Greenwood Avenue, Suite 600, Jenkintown, PA 19046. Plaintiff resides at 126 West Washington Lane, Philadelphia, PA 19144.

7. Defendant FDA is an administration in the Department of Health and Human Services, located at 10903 New Hampshire Avenue, Silver Spring, Maryland. FDA is charged with regulating drugs marketed in the United States. Defendant FDA is an agency within the meaning of 5 U.S.C. § 552(f). Defendant FDA has possession of and control over certain records and documents that Plaintiff seeks.

IV. LEGAL AND FACTUAL BACKGROUND

8. The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman") provides for generic drug approval pursuant to an ANDA wherein an applicant demonstrates that its generic is "bioequivalent" to the brand.

9. A Summary Basis of Approval ("SBA") is a document maintained by FDA that contains a summary of the information evaluated by FDA during the approval process for each ANDA, including the final reviews of each of the review divisions within the FDA, and a section commonly titled "Administrative and Correspondence Documents" that contains "[a]ll

correspondence and written summaries of oral discussions between FDA and the applicant relating to the application." 21 C.F.R § 314.430(e)(7) (2011). Once FDA sends a letter approving an ANDA, the SBA relating to that ANDA is "immediately available for public disclosure." 21 C.F.R. § 314.430(e) (2011).

10. FOIA provides that "each agency, upon any request for records which . . . reasonably describes such records and . . . is made in accordance with [the] published rules . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A).

11. Under FOIA, FDA must "determine within 20 days . . . after the receipt of any such request whether to comply with such request and shall immediately notify the [requestor] of such determination and the reasons therefor[.]" 5 U.S.C. § 552(a)(6)(A)(i).

12. In accordance with FOIA, FDA regulations state that "[e]xcept where specifically exempt . . . all Food and Drug Administration records shall be made available for public disclosure." 21 C.F.R. § 20.20(b) (2009). "Within 20 working days . . . after a request for records is logged in at the Freedom of Information Staff, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial." 21 C.F.R. § 20.41(b).

13. Once a determination to comply with a FOIA request is made, "the records *shall be made promptly available*" to the requestor unless the government can show "exceptional circumstances exist." 5 U.S.C. § 552(a)(6)(C)(i) (emphasis added).

14. When an agency fails to respond within the statutory time frame, the requester will be deemed to have exhausted its administrative remedies and may seek relief in federal court. 5 U.S.C. § 552(a)(6)(C)(i).

15. Upon information and belief is has long been the practice of FDA to answer all requests classified as "complex" (i.e., expected to take more than a few hours of search and review time) by stating that production of the requested documents will take at least 18-24 months to process.

V. FACTS

16. On April 5, 2012, Plaintiff submitted a FOIA request to FDA's Division of Freedom of Information requesting the SBAs for ANDAs 076565 (Teva), 078057 (Impax Labs), and 078789 (Mylan).

17. Upon information and belief, SBAs are prepared and appropriately redacted as a matter of course following final FDA approval of a drug product.

18. Plaintiff received a form letter from FDA dated April 9, 2012 acknowledging receipt of Plaintiff's FOIA request, assigning control number 2012-2588, and stating that FDA "will respond as soon as possible[.]"

19. During a telephone conversation on June 5, 2012, an FDA representative stated that it would take approximately two years to produce responsive documents.

20. Plaintiff attempted to negotiate a modified FOIA request scope and response timetable before it became clear that, to qualify for the "simple" queue, the FOIA request would need to be far too narrow to be useful to Plaintiff. In particular, Plaintiff sought prompt production of a small fraction of each SBA requested, the review of which might reduce or eliminate Plaintiffs need for the remainder. FDA stated that unless Plaintiff could narrow the scope of its request to, e.g., a "single letter" from each SBA, and simultaneously agree to abandon the entire remainder of the FOIA request, no documents would be produced for approximately two years.

21. As of the date of this complaint – nearly six months since FDA received Plaintiff's FOIA request – FDA has not produced any responsive documents.

22. FDA's failure to respond within twenty working days to Plaintiff's FOIA request, and its failure to produce responsive documents promptly, constitutes a violation of the Act and FDA regulations. 5 U.S.C. § 552(a)(6)(A)(i), 21 C.F.R. § 20.41(b).

23. Under § 552(a)(6)(C)(i), Plaintiff has exhausted his administrative remedies with respect to this FOIA request because FDA failed to comply with the applicable time limit provisions of 5 U.S.C. § 552(a)(6)(A)(i).

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this court:

A. Order FDA to promptly produce to Plaintiff the records and documents requested in the FOIA request;

B. Enjoin Defendant FDA from withholding the records and documents requested in the FOIA request;

C. Award Plaintiff costs and reasonable attorney's fees pursuant to 5 U.S.C. § 552(a)(4)(E); and

D. Grant such other relief as the Court deems just.

Dated: September 10, 2012

Respectfully Submitted,

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